UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,259	07/26/2007	Remo Kranich	014.0005-US00	6454

92049 7590 03/08/2012

J.A. Lindeman & Co. PLLC
3190 Fairview Park Drive
Suite 480
Falls Church, VA 22042

EXAMINER	
CORNET, JEAN P	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/08/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jeff.lindeman@jalindeman.com
mail@jalindeman.com
rhonda.grant@jalindeman.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,259	KRANICH ET AL.	
	Examiner	Art Unit	
	JEAN CORNET	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2012*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *11-14 and 17-19* is/are pending in the application.

5a) Of the above claim(s) *14* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *11-13 and 17-19* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/05/2012 and 02/22/2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-14 and 17-19 are pending. Claims 14 remain withdrawn. Claims 1-10 and 15-16 are canceled. Claims 11-13 and 17-19 are currently under examination.

The amendment filed on 02/22/2012 in response to the Non-Final office Action of 10/05/2011 is acknowledged and has been entered.

Information Disclosure Statement

All of the references cited in the IDS submitted on 01/05/2012 and 02/22/2012 have been considered except for JP2003-055369 A which is not in English.

Double Patenting

Response to Arguments

Applicant's arguments, with respect to double patenting have been fully considered and are persuasive. The rejection of claims 11-13 and 17-19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 of US patent 7,919,532 has been withdrawn due to the filing of a terminal disclaimer.

Terminal Disclaimer

The terminal disclaimer filed on 02/06/2012 disclaiming the terminal portion of any patent granted on this application has been reviewed and is accepted. The terminal disclaimer has been recorded.

New Rejection necessitated by the filing of copending application 12/941,369 corresponding to US Pub no. 2011/0053939, WO2007/039111 corresponding to copending application no. 12/066,757, WO2007/039112 corresponding to application no. 13/032,760, US Patent 7,923,473 and US Patent 7/851,501 in IDS dated

Double Patenting

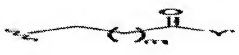
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 and 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 9, 10 and 11 of **U.S. Patent No. 7,823,473** B in view of Patani, already of record and Appeldoorm et al, Journal of Biochemical Chemistr, Vol. 278, No. 12, March, 2009, pp. 10201-10207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the copending claims are drawn to the same formula where

-X' is



Y' is

or

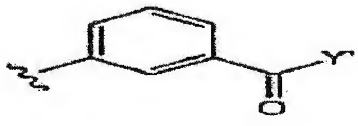
And all other substituents overlap for modulating the in vitro and in vivo processes mediated by E-selectin, P-selectin or L-selectin. The only difference is the instant claims recite 3,4,5-trihydroxyphenyl whereas the US Patent claims recite 3,4,5-trimethoxyphenyl.

Patani teaches a lead compound with a desired pharmacological activity may have associated with it undesirable side effects, characteristics that limit its bioavailability, or structural features which adversely influence its metabolism and excretion from the body; bioisosterims represents one approach used by the medicinal chemist for the rational modification of lead compounds into safer and more clinically effective agents (p. 3147, 1st paragraph); the ability of a group of bioisosteres to elicit similar biological activity has been attributed to common physicochemical properties; physicochemical effects such as electronegativity, steric size, and lipophilicity have been correlated to observed biological activity in the review (p. 3148, 2nd paragraph); bioisosteres include methyl for hydrogen, Grimm's Hydride Displacement Law (p. 3152, section 4).

Additionally, Appeldoorn et al teach the number of exposed hydroxyl groups appear to be critical for P-selecting affinity and the 3,4,5-trimethoxyphenyl group is more active than the mono and the di and more importantly, P-selectin binding was completely abolished after conversion of the hydroxyl group into methyl esters, (see p. 10205, first col bridging second col).

It would have been obvious to one of ordinary skill at the time of the instant invention to replace all three CH3 group with the bioisosteric H, giving the instant compounds and compositions because Appeldoorn et al teach methyl esters on the phenyl ring abolishes P-selecting binding. The motivation would have been to prepare compounds with similar activities.

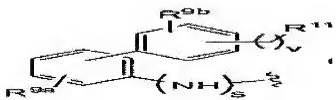
. Claims 11-13 and 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of **U.S. Patent No. 7,851,501 B2** in view of Appeldoorm et al, Journal of Biochemical Chemistr, Vol. 278, No. 12, March, 2009, pp. 10201-10207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the copending claims are drawn to the same formula where X is



And

Y' is

or



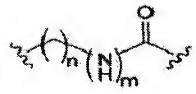
And all other substituents overlap for modulating the in vitro and in vivo processes mediated by E-selectin, P-selectin or L-selectin. The only difference is the instant claims have three OH on

the phenyl ring of the formula C and D whereas the US Patent claims have 2 OH and a NO2 on the phenyl ring of the formula (IIB) or (IIC).

Appeldoorn et al teach a phenyl ring with 3-OH has a better binding affinity than a phenyl ring with a nitro group, (see Fig. 4). In addtion, Appeldoorn et al teach the number of exposed hydroxyl groups appear to be critical for P-selectin affinity and the 3,4,5-trimethoxyphenyl group is more active than the mono and the di-hydroxylated phenyl group and more importantly, P-selecting binding was completely abolished after conversion of the hydroxyl group into methyl esters, (see p. 10205, first col bridging second col).

It would have been obvious to one of ordinary skill at the time of the instant invention to replace the nitro group on the phenyl ring with an OH group, giving the instant compounds and compositions because Appeldoorn et al teach phenyl ring with three OH, specifically the 3,4,5-trimethoxyphenyl group appears to be critical for P-selectin binding. . The motivation would have been to prepare compounds with similar activities.

Claims 11-13 and 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 **of copending application No.12/941,369** in view of Appeldoorm et al, Journal of Biochemical Chemistr, Vol. 278, No. 12, March, 2009, pp. 10201-10207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the copending claims are drawn to the same formula where X is



And all other substituents overlap for modulating the in vitro and in vivo processes mediated by E-selectin, P-selectin or L-selectin. The only difference is the instant claims have three OH on the phenyl ring of the formula C and D whereas the US Patent claims have 2 OH and a NO2 on the phenyl ring of the formula (IIB) or (IIC).

Appeldoorn et al teach a phenyl ring with 3-OH has a better binding affinity than a phenyl ring with a nitro group, (see Fig. 4). In addtion, Appeldoorn et al teach the number of exposed hydroxyl groups appear to be critical for P-selectin affinity and the 3,4,5-trimethoxyphenyl group is more active than the mono and the di and more importantly, P-selecting binding was completely abolished after conversion of the hydroxyl group into methyl esters, (see p. 10205, first col bridging second col).

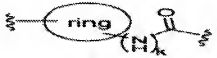
It would have been obvious to one of ordinary skill at the time of the instant invention to replace the nitro group on the phenyl ring with an OH group, giving the instant compounds and compositions because Appeldoorn et al teach phenyl ring with three OH, specifically the 3,4,5-trimethoxyphenyl group appears to be critical for P-selectin binding. . The motivation would have been to prepare compounds with similar activities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-13 and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 13-17 of **copending Application No. 12/066,757** in view of Patani, already of record and Appeldoorm et al, Journal of Biochemical Chemistr, Vol. 278, No. 12, March, 2009, pp. 10201-10207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the copending claims are drawn to the same formula where

-X- =

(b)



wherein "ring" is

wherein R' is H, NO_2, CF_3, F, Cl, Br, I, CN, CH_3, NH_2, NHAlkyl, NHAryl, NHAcyl, and k = 0

And all other substituents overlap for modulating the in vitro and in vivo processes mediated by E-selectin, P-selectin or L-selectin. The only difference is the instant claims recite 3,4,5-trihydroxyphenyl whereas the copending claims are limited to 2-OH groups.

Patani teaches a lead compound with a desired pharmacological activity may have associated with it undesirable side effects, characteristics that limit its bioavailability, or structural features which adversely influence its metabolism and excretion from the body; bioisosterims represents one approach used by the medicinal chemist for the rational modification of lead compounds into safer and more clinically effective agents (p. 3147, 1st paragraph); the ability of a group of bioisosteres to elicit similar biological activity has been attributed to common physicochemical properties; physicochemical effects such as

electronegativity, steric size, and lipophilicity have been correlated to observed biological activity in the review (p. 3148, 2nd paragraph); bioisosteres include OH and H substituted on a phenyl ring (p. 3152, Table 9; p.3153, Table 12).

Additionally, Appeldoorn et al teach the number of exposed hydroxyl groups appear to be critical for P-selecting affinity and the 3,4,5-trimethoxyphenyl group is more active than the mono- and the di-hydroxylated phenyl group and more importantly, P-selectin binding was completely abolished after conversion of the hydroxyl group into methyl esters, (see p. 10205, first col bridging second col).

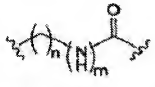
It would have been obvious to one of ordinary skill at the time of the instant invention to replace any on the hydrogen atom of the phenyl ring with the bioisosteric OH group, giving the instant compounds and compositions because Appeldoorn et al teach the 3,4,5-trimethoxyphenyl group is more active than the mono- and the di-hydroxylated phenyl group for P-selectin binding. The motivation would have been to prepare compounds with similar activities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Claims 11-13 and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 10 of **copending Application No. 13/032,7960** in view of Appeldoorm et al, Journal of Biochemical Chemistr, Vol. 278, No. 12, March, 2009, pp. 10201-10207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the copending claims are drawn to the same formula where

–X– is

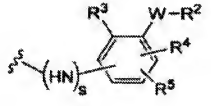
(a)



with m = 0 or 1; n = an integer from 1 to 3;

–Y is

(a)



in which s is 0 or 1;

R^2 is CO_2H, CO_2alkyl, CO_2aryl, CO_2NH_2, CO_2aralkyl, CH_2SO_3H, $CH_2SO_2NH_2$, $CH_2PO_2(OH)_2$, SO_3H, SO_2NH_2, $PO(OH)_2$, 1-H-tetrazolyl-, CHO, $COCH_3$, CH_2OH,

And all other substituents overlap for modulating the in vitro and in vivo processes mediated by E-selectin, P-selectin or L-selectin. The only difference is the instant claims recite 3,4,5-trihydroxyphenyl whereas the copending claims are limited to 2,4,6-trihydroxyphenyl. In other words they are positional isomers. Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA

1977). See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious).

Appeldoorn et al teach the number of exposed hydroxyl groups appear to be critical for P-selecting affinity and the 3,4,5-trimethoxyphenyl group is more active than the mono- and the di-hydroxylated phenyl group and more importantly, P-selectin binding was completely abolished after conversion of the hydroxyl group into methyl esters, (see p. 10205, first col bridging second col).

It would have been obvious to one of ordinary skill at the time of the instant invention to position the OH groups at position 3,4,5 of the phenyl ring to give the instant compounds and compositions because it is known that position isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. This is also evidenced by the teaching of Appeldoorn et al. Appeldoorn et al teach the 3,4,5-trimethoxyphenyl group is more active than the mono- and the di-hydroxylated phenyl group for P-selectin binding. The motivation would have been to prepare compounds with similar activities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Conclusion

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 01/05/2012 prompted the new ground(s) of rejection

presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Thursday 7.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628